K130794

Veridex, LLC.
1001 US Highway 202
Raritan, NJ 08869

JUN 20 2013

8.0 510(K) SUMMARY

Submitter's Name	Veridex, LLC
Address	1001 US Highway 202 Raritan, NJ 08869-0606
Telephone Number **Fax Number**	908-927-4947 908-526-5059
Contact Person	Kimberly Prescott, Associate Director, Global Regulatory Affairs
Date:	March 20, 2013
Name of the Device	CELLTRACKS ANALYZER II® System
Common or Usual Name	Immunomagnetic circulating cancer cell selection and enumeration system
Classification Name	Immunomagnetic circulating cancer cell selection and enumeration system Device Class: II Product Code: NQI Regulation Number: 21 CFR 866.6020
Performance Standards	There are no performance standards promulgated for this device.
Indications for Use	The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immunomagnetically selected and aligned. This product is for in vitro diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for in vitro diagnostic use with this device..
Identification of the Legally Marketed Device (Predicate Device)	CELLTRACKS ANALYZER II® System Name: Immunomagnetic circulating cancer cell selection and enumeration system Device Class: II Product Code: NQI Regulation Number: 21 CFR 866.6020

510(k) Summary, continued

Device Description	The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope, consisting of the analyzer, a dedicated computer with CELLTRACKS® software, monitor, keyboard, mouse and uninterruptible power supply (UPS). The system also supports an optional Remote Review Workstation, which consists of a dedicated computer with CELLTRACKS® software, monitor, keyboard and mouse. Use of this product requires training and should be used under the supervision of laboratory management. The CELLTRACKS ANALYZER II® is for analysis of rare cells that are isolated from biological fluids including whole blood. It is used in conjunction with the CELLTRACKS® AUTOPREP® System, which automates and standardizes the sample preparation with specific reagent kits. The optional Remote Review Workstation provides the capability to review images and report results remotely.
Comparison to Predicate Device	The CELLTRACKS ANALYZER II® (modified) is substantially equivalent to the CELLTRACKS ANALYZER II® (current - K113181, December 12, 2011). There has been no change to intended use, fundamental scientific technology, mode of operations, or specimen type/identification. There are 2 main modifications to the current CELLTRACKS ANALYZER II® (K118131, cleared December 12, 2011) that are included in this Traditional 510(k) submission: • The CELLTRACKS ANALYZER II® Software has been modified to version 2.6.0, and is present on both the CELLTRACKS ANALYZER II® PC and the Remote Review Workstation PC. • A Remote Review Workstation PC is now available, supporting identical image review and result reporting functionality that is currently supported locally on the CELLTRACKS ANALYZER II®.
Description of Testing	Non-clinical testing for the CELLTRACKS ANALYZER II® System included: • Unit/Integration/System Verification • System Level Validation • Stress Testing • Regression Testing • Control Cell/Sample Performance Validation Testing

Conclusion of Testing	The information presented in the premarket notification demonstrates that the performance of the CELLTRACKS ANALYZER II® System (modified) is substantially equivalent to the predicate device. Equivalence was demonstrated through non-clinical functional testing for the modified device. The information presented in the premarket notification provides a reasonable assurance that the CELLTRACKS ANALYZER II® System (modified) is as safe and effective as the predicate device for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

VERIDEX, LLC
C/O MS. KIMBERLY PRESCOTT
ASSOCIATE DIRECTOR, GLOBAL REGULATORY AFFAIRS
1001 US HIGHWAY 202
RARITAN NJ 08869

Re: K130794
Trade/Device Name: CELLTRACKS ANALYZER II® System
Regulation Number: 21 CFR 866.6020
Regulation Name: Immunomagnetic circulating cancer cell selection and enumeration system
Regulatory Class: II
Product Code: NQI
Dated: June 10, 2013
Received: June 13, 2013

Dear Ms. Prescott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130794

Device Name: CELLTRACKS ANALYZER II® System

Indications For Use:

The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immunomagnetically selected and aligned. This product is for in vitro diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for in vitro diagnostic use with this device.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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